

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/	)	
FENFLURAMINE/DEXFENFLURAMINE)	)	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION	)	
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS	)	2:16 MD 1203
CORPORATION	)	

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

Bartle, J.

July 20, 2011

Christine A. Zaffran ("Ms. Zaffran" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Kenneth B. Zaffran, Ms. Zaffran's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D., F.A.C.C. Based on an echocardiogram dated September 25, 2002, Dr. Ansari attested in Part II of Ms. Zaffran's Green Form that she suffered from moderate mitral

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3. (...continued)

(Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

regurgitation,<sup>4</sup> pulmonary hypertension second to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.<sup>5</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.<sup>6</sup>

In the report of claimant's echocardiogram, Dr. Ansari stated that claimant had "moderate mitral regurgitation, which occupied 39% of the left atrial surface." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

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4. Dr. Ansari also attested that claimant suffered from moderate aortic regurgitation. As Ms. Zaffran's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this case. See Settlement Agreement § IV.B.2.c.(2) (a).

5. Dr. Ansari also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2) (b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim. As the Trust concedes that Ms. Zaffran suffers from pulmonary hypertension, the only issue is claimant's level of mitral regurgitation.

In October, 2005, the Trust forwarded the claim for review by David I. Silverman, M.D., one of its auditing cardiologists. In audit, Dr. Silverman concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild regurgitation. In support of this conclusion, Dr. Silverman explained that claimant had a "[m]aximum RJA/LAA ratio [of] 4/21=19%, below [the] threshold for moderate [mitral regurgitation]."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Zaffran's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that there was a reasonable medical basis for Dr. Ansari's Green Form representation that Ms. Zaffran suffered from moderate mitral regurgitation. Claimant submitted a letter from Dr. Ansari wherein he stated that he again reviewed Ms. Zaffran's echocardiogram and confirmed that her level of

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Zaffran's claim.

mitral regurgitation was moderate at 30% to 33%, and not mild. In support, Dr. Ansari attached several still-frame images, which purportedly demonstrated moderate mitral regurgitation, and explained, "Computer-assisted visual assessment indicates [19% regurgitation] is impossible.... Only three index jets (33%) can fit in two different LAAs...."

The Trust issued a final post-audit determination, again denying Ms. Zaffran's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Zaffran's claim should be paid. On April 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6223 (Apr. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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8. (...continued)  
and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Zaffran reasserts the arguments that she made in contest, namely, that there is a reasonable medical basis for Dr. Ansari's Green Form representation that claimant had moderate mitral regurgitation.

In response, the Trust argues that Dr. Ansari's letter does not provide a reasonable medical basis for his Green Form representation because "the measurements upon which Dr. Ansari relies are neither reliable nor representative." The Trust contends that these measurements were taken from very early systole near the QRS complex, consistent with backflow, and are "overtraced to include non-regurgitant flow and [are], in any event, not seen in [claimant's] real-time echocardiogram study." The Trust further contends that "the LAA measurement upon which Dr. Ansari relies was taken during early systole, when the left atrium is at its smallest, resulting in a marked underestimation of Respondent's true LAA and, in turn, further exaggeration of Respondent's supposed RJA/LAA ratio."

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Burke determined that:

... I found the planimetered areas on the tape representative of those noted in real-time. The planimetered areas were reasonably done. They specifically excluded backflow.

The left atrial planimetered area measurement also appeared to be done correctly and probably from the same frame as the RJA (regurgitant jet area) measurement.

....

Using representative beats in the apical four chamber view, I calculated the RJA/LAA ratios to range from 22% to 47%. These ratios are in the range for moderate to severe mitral regurgitation.

Using representative beats in the apical three chamber view, calculated the RJA/LAA ratios to range from 25% to 36%. This represents moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Ansari, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Without adequate support, the Trust challenged the attesting physician's finding and argued that his measurements were not reliable or representative. Dr. Burke, however, reviewed claimant's echocardiogram and determined that Ms. Zaffran's RJA/LAA ratio in the apical four chamber view ranged from 22% to 47% and in the apical three chamber view ranged from 25% to 36%. In addition, Dr. Burke specifically determined that Dr. Ansari's measurements were representative, not overtraced, and did not include backflow.<sup>9</sup>

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9. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.



For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of Ms. Zaffran's claim for Matrix Benefits and the related derivative claim submitted by her spouse.